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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/518,513

12/21/2004

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3003-1159

8360

466

7590

02/10/2009

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

02/10/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.



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## DETAILED ACTION

### *Claim Objections*

1. Claims 12 and 14-17 are objected to because of the following informalities:
2. claim 12, line 17: "peripheral thickened region" should read "peripheral thickened rib"
3. claim 14, line 3: "thickened region" should read "thickened rib"
4. claim 15, line 16: "peripheral thickened hollow region" should read "peripheral thickened hollow rib"
5. claim 16, line 4: "thickened hollow region" should read "thickened hollow rib"; also, there appears to be a word omitted between "edge" and "thickened".
6. claim 17, line 3: "thickened region" should read "thickened rib"

### *Claim Rejections - 35 USC § 103*

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. **Claims 12 and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall et al. (US 5,487,748; "Marshall") in view of Morita (US 5,628,765). Marshall discloses a lancet comprising a needle having a pointed tip, a support body (8) enclosing the needle such that the pointed tip (19) projects beyond the end of the support body, and a removable guard (20, 22) located over the pointed tip of the needle, the guard made from molded plastics material and connected thereto by a breakable neck portion (21). The removable guard portion has a region of thinner section (22) and a tip encasing region (20) encasing the tip of the needle (fig. 1 shows side view) wherein the tip encasing region is thicker than the thinner section (22).

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Marshall discloses that various parts of the device are made from molded plastics but fails to expressly disclose that the guard is integrally molded with the support body. However, since the support body and guard are connected by a frangible neck, it would have been obvious to use a single mold to form the connected pieces. Marshall also fails to disclose the claimed peripheral thickened rib.

9. Morita teaches that it is well known to include a u- or c-shape peripheral thickened rib around a central region of thinner section on a removable guard ("98; fig. 10 and 11). The thickened rib is advantageous because it facilitates gripping of the guard for its removal. It would have been obvious to one skilled in the art to add such an outer peripheral thickened rib as taught by Morita to the device of Marshall so that it too would have this advantage. With this rib, the thinner region (22 inside of thicker rib taught by Morita) can be considered a central region of thinner section than the rib which is partly surrounded by the rib. The tip encasing region is spaced from the adjacent ends of the rib such that there are respective gaps therebetween bridged only by the thinner central section.

10. **Claims 13 and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Morita as applied to claim 12 above and further in view of Crossman (GB 2,352,403). Marshall in view of Morita discloses the invention substantially as stated above except for a hole positioned close to the end of the guard remote from the needle point.

11. Crossman discloses that is well known to have a hole (8) formed in the distal end of a plastic injection-molded guard (figs. 1-3). Adding such a hole to the modified device of Marshall would have been an obvious modification because the hole does not interfere with the encasing of the needle tip and advantageously decreases the amount of material needed to manufacture the guard. Regarding claim 17, the guard is tab-like with a thickened rib as taught by Morita.

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12. **Claim 15** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Morita and Higgins (US 3,358,689). Marshall in view of Morita discloses a lancet having the claimed structure and Morita teaches forming the lancet using plastic injection molding process wherein a mold is constructed with cavities arranged to result in the structure of the lancet above (col. 7 ll. 23-29). In order to attain the structure of the lancet of Marshall in view of Morita as discussed in detail above with respect to claim 12, it would have been obvious to construct the mold to have an outer peripheral thickened hollow region of generally u or c shape which leads to a thinner hollow section and a further enlarged hollow region encasing the needle spaced from the ends of the peripheral thickened hollow region to leave a gap therebetween that is bridged only by the thinner hollow section. Morita does not expressly teach an entry point for the plastics material at an end remote from the needle point. However, Higgins discloses that it is well known to provide an entry point (88) in a lancet guard mold at an end of the guard remote from the pointed needle tip and it would have been obvious to provide such an entry point positioned in this manner on the mold of Morita as it provides a way of delivering the plastics material.

13. **Claim 16** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marshall in view of Morita and Higgins as applied to claim 15 above, and further in view of Crossman (GB 2,352,403). Marshall in view of Morita and Higgins discloses the invention substantially as stated above except for a hole positioned close to the end of the guard remote from the needle point as well as a pin to cause the plastics material to flow around pin, thereby forming the hole.

14. Crossman discloses that is well known to have a hole (8) formed in the distal end of a guard (figs. 1-3). Adding such a hole to the modified device of Marshall would have been an obvious modification because the hole does not interfere with the encasing of the needle tip and advantageously decreases the amount of material needed to manufacture the guard. Crossman

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discloses that pins can be used to form holes in an injection molded plastics body (p. 3 ll. 7-9) and it would have been obvious to use such a pin to form the hole in the guard.

### ***Response to Arguments***

15. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 2/5/2009

/Anh Tuan T. Nguyen/  
Supervisory Patent Examiner, Art Unit 3731